UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CITY OF HUNTINGTON,
Plaintiff,
v.
AMERISOURCE BERGEN DRUG CORPORATION, et al.,
Defendants.

Civil Action No. 3:17-cv-01362

CABELL COUNTY COMMISSION,
Plaintiff,
v.
AMERISOURCE BERGEN DRUG CORPORATION, et al.,
Defendants.

Consolidated case:
Civil Action No. 3:17-cv-01665

PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING DEFENDANTS' STATUTORY AND REGULATORY DUTIES

Contrary to the Defendants' contentions in their Notice of Supplemental Authority, the Drug Enforcement Administration's ("DEA") recently-issued Notice of Proposed Rulemaking ("Proposed Rules"), 85 Fed. Reg. 69282 (Nov. 2, 2020), confirms that, under the Controlled Substances Act ("CSA") and its implementing regulations, Defendants have always been under a duty to refrain from shipping suspicious orders

("the shipping duty").[1] The Proposed Rules expressly state that "identifying and reporting suspicious orders of controlled substances (and refusing to distribute based on such orders), ***has always been, and remains,*** the responsibility of the DEA registrant." Proposed Rules, 85 Fed. Reg. at 69283-84 (emphasis added); *see also id.* at 69284 (CSA and regulations contain five obligations, including the obligation "to refuse to distribute controlled substances that are likely to be diverted into illegitimate channels").[2] The DEA further noted that "at various times, and in various places and manners, some registrants have failed to fulfill their obligations." *Id.* at 69284. Specifically, referring to past practices, the DEA explained that some "registrants filed suspicious order reports, but then distributed controlled substances pursuant to the order anyway—failing to conduct due diligence prior to distributing controlled substances . . ." *Id.* To address this problem of noncompliance, the DEA has issued the Proposed Rules to clarify existing obligations, including the obligation not to ship suspicious orders until they have been cleared through due diligence.

[1] Although Plaintiffs have most often referred to this as a "no-shipping" duty, in the Proposed Rules, the DEA uses the term "shipping duty." Plaintiffs here follow the DEA's practice and use the term "shipping duty."

[2] *See also id.* at 69287 ("in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted"); *id.* ("To maintain effective controls against diversion, the registrant should exercise due care in confirming the legitimacy of all orders *prior to* filling") (emphasis added); *id.* ("Registrants must conduct an independent analysis of suspicious orders *prior to* completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. . . . Registrants that . . . fill these orders without first determining that order is not being diverted, may be failing to maintain effective controls against diversion.") (emphasis added).

Indeed, the DEA described the Proposed Rules as a clarification eight times,[3] removing any possible doubt that the duties discussed in the Proposed Rules already exist under the CSA.

The new Proposed Rules are thus entirely consistent with both Plaintiffs' position in the instant motion and the prior decisions of both the DEA and the three federal courts that have had the opportunity to address the issue.[4] Contrary to Defendants' representations, as the above-quoted text makes clear, the purpose of the Proposed Rules was not to add the shipping requirement, which the text acknowledges has long been established. *See* Proposed Rules, Section IV.D ("The Due Diligence Requirement"), *id.* at 69286-87. Rather, the Proposed Rules were designed to implement the centralized reporting requirements of the Preventing Drug Diversion Act of 2018, to add definitions and uniform procedures to bring greater clarity and consistency to the existing CSA requirements, and to streamline reporting procedures with respect to suspicious orders that can be quickly cleared through `due diligence. *Id.* at 69282, 69283, 69292.

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[3] 85 Fed Reg. 69282, 69283, 69285, 69287, 69288, 69290.

[4] *See Masters Pharmaceuticals Inc., Decision and Order,* 80 FR 55418-01, 2015 WL 5320504 (DEA September 15, 2015), *aff'd, Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213, 222 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 2007 WL 1886484 (DEA July 3, 2007); *In re Nat'l Prescription Opiate Litig.,* No. 1:17-md-2804, 2019 WL 3917575, at *7-9 (N.D. Ohio Aug. 19, 2019); *City and County of San Francisco v. Purdue Pharma, LP, et al.,* No. 3:18-CV-07591-CRB, 2020 WL 5816488 at *3-4 (N.D. Cal. Sep. 30, 2020).

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The Proposed Rules are the latest in a long, consistent string of judicial and administrative determinations holding that the CSA and its implementing regulations impose a duty on Defendants to halt and investigate suspicious orders prior to shipping. The Proposed Rules confirm Plaintiffs' legal position. The Court should grant Plaintiffs' Motion for Partial Summary Judgment Concerning Defendants' Statutory and Regulatory Duties and hold that that Defendants had the duties under the CSA and its implementing regulations to design and operate a system to disclose suspicious orders, inform the DEA of suspicious orders when discovered, and not to ship suspicious orders without performing due diligence.

Dated: November 20, 2020

THE CITY OF HUNTINGTON

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CERTIFICATE OF SERVICE

I certify that on November 20, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ *Anthony J. Majestro*